In the Claims

9. (Amended) A composition comprising a mixture of an optically pure isomer of albuterol and at least one additional drug.

10. (Amended) A composition of Claim 9 [containing] wherein the albuterol contains at least 90% by weight of the R(-) isomer of albuterol.

11. (Amended) A composition of Claim 10 [containing] wherein the albuterol contains at least 99% by weight of the R(-) isomer of albuterol.

REMARKS

Applicants' Invention

The invention is a method for treating asthma by administering to an afflicted individual an optically pure R(-) isomer of albuterol. Racemic mixtures of drugs, including albuterol, suffer from several drawbacks, including side effects associated with one isomer but not the other, and the fact that only one isomer generally has the therapeutic effect. Higher doses of the racemic mixture must be administered than of the optically pure active isomer. The present method solves many of the problems associated with racemic albuterol.

Rejection of Claims 1-12 Under 35 U.S.C. 103

Claims 1-12 are rejected under 35 U.S.C. 103 as being unpatentable over the Chemical Abstracts reference, which, the Office Action states, teaches

salbutamol (albuterol) to treat asthma. The Office Action states that the determination of a particular isomer to employ would be a matter of obvious alternatives.

The Chemical Abstracts reference (89:123259) describes the results of a comparison of the broncodilator effects in asthmatic patients of salbutamol (albuterol), a mixture of salbutamol with hydroxyzine, and a mixture of ephedrine, hydroxyzine and theophylline. The abstract reports that there was little difference between the three combinations in terms of effectiveness or side effects.

Applicants' method utilizes an optically pure isomer of albuterol to treat asthma while reducing the side effects associated with the drug, e.g., drowsiness and cardiac disturbances. Such a method is neither taught nor suggested by the cited abstract. The abstract teaches that albuterol is not any more effective in treating asthma than other known drugs, such as theophylline, and the abstract does not teach or suggest utilizing an optical isomer of albuterol or any other drug. Thus, one skilled in the art relying upon the cited reference would not have been motivated to practice the claimed method, since there is no teaching or suggestion that the active optical isomer of a drug could be administered or would be more effective than the racemic mixture if it was.

The Examiner has cited In re Adamson et al., 125 USPQ 233 (CCPA, 1960) in support of his statement that differences in activity between optical isomers is not unexpected. In this case, the claims on appeal were composition claims directed to the levo-isomer of the cited compounds. Process claims drawn to separating

the levo-isomer from the dextro isomer were also considered. The CCPA upheld the Board of Appeals' decision affirming the Examiner's rejection of the claims based on prior art showing that many biological compounds exist as optical isomers and that the specific claimed compounds were known to be racemic mixtures. This case is not applicable to the instant case, in which the claims are drawn to a method of treating asthma by administering the R(-) isomer of albuterol. The art cited by the Examiner shows that racemic albuterol has been administered for treating asthma. However, there is no teaching or suggestion of administering the R(-) isomer of albuterol, or, in fact, of administering an optical isomer of any drug. This is important because optical isomers are chemically identical but may have profoundly different biological effects. For example, one isomer of a chiral compound may be biologically active while its' enantiomer, which is chemically and physically identical, may have little or no biological effect, or may have adverse effects. Such behavior cannot be predicted a priori, however. Therefore, one skilled in the art would be familiar with the biological and pharmcological unpredictability of enantiomers of a compound, and the claimed method would not have been obvious to such a person relying upon the cited abstract.

Rejection of Claims 9-12 Under 35 U.S.C. 112, second paragraph

Claims 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

subject matter which Applicants regard as the invention. The Office Action states that the claims lack proportions of ingredients, and that the amount of the R isomer appears to relate to the entire composition rather than total albuterol. Claims 9-11 have been amended to more clearly recite the proportions of ingredients. The amendments to the claims obviate this rejection.

Information Disclosure Statement

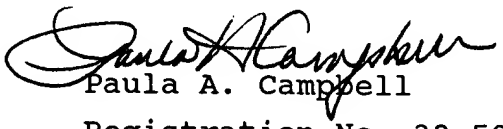
An Information Disclosure Statement is being submitted herewith.

CONCLUSION

In view of the amendments to the claims and the arguments presented herein, Applicants respectfully request that the above rejections be reconsidered and withdrawn.

If the Examiner believes that a telephone conversation with Applicants' attorney would be helpful in expediting prosecution of the application, the Examiner is invited to call the undersigned attorney at 617-861-6240.

Respectfully submitted,



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